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National heart transplantation study

Background

In 1980, the Health Care Financing Administration (HCFA) was asked by the Secretary of the Department of Health and Human Services (DHHS) to make a decision about Medicare coverage and reimbursement of heart transplant procedures. As administrator of the Medicare program, HCFA is routinely asked to render such judgements. Recognizing the complexity of the issues involved, HCFA contracted with the Battelle Human Affairs Research Centers in Seattle, Wash., to conduct a comprehensive study of heart transplantation (HCFA Contract No. 500-81-0051). The purpose of the study was to "...examine, in general, all aspects of heart transplants, including the scientific, social, economic, and ethical issues and, in particular, the impact of a possible Medicare decision to pay for heart transplants on the Medicare program, Medicare beneficiaries, and providers of health care." This 3-year study began October 1981. The project director for Battelle Human Affairs Research Center was Roger W. Evans and the project officer from the Office of Research and Demonstrations was Joel H. Broida.

Participating institutions

There were six medical centers selected to participate in the study. They are as follows:

- University of Arizona Health Sciences Center, Tucson, Ariz.
- Columbia Presbyterian Medical Center, New York, N.Y.
- Medical College of Virginia, Richmond, Va.
- University of Minnesota, Minneapolis, Minn.
- University of Pittsburgh, Pittsburgh, Pa.
- Stanford University Medical Center, Stanford, Calif.
- Data were obtained from these centers on 441 heart transplant recipients, including 152 living heart transplant recipients. Data were compiled on all patients transplanted since 1968.

History

Some historical highlights follow:

- The first human heart transplant was performed on December 3, 1967, by Dr. Christiaan Barnard in Capetown, South Africa.
- Dr. Adrian Kantrowitz performed the first heart transplant in the United States on December 6, 1967, at Maimonides Hospital in Brooklyn, N.Y.
- More than 900 heart transplants have now been performed in the United States.
- In 1983, 172 heart transplants were performed in the United States. It is estimated that 225 were performed in 1984.
- There are currently 25 active heart transplant programs in the United States.
- Stanford University Medical Center has the most active heart transplant program in the United States; the first heart transplant was performed there by Dr. Norman Shumway on January 6, 1968.

Patient description

Patients with end-stage cardiac disease who received heart transplants were similar to those who needed the procedure, a perfect correspondence did not exist.

- The average age of a living heart transplant recipient was 42.4 years.
- 87.5 percent of living heart transplant recipients were male.
- 87.5 percent of living heart transplant recipients were white.
- 73 percent of living heart transplant recipients were married.
- 51 percent of all living heart transplant recipients had cardiomyopathy as their primary disease diagnosis. 37.3 percent had artery disease, and the remainder had a variety of other end-stage cardiac diseases.

Need for heart transplantation

The need for heart transplantation is largely a function of the criteria developed by a panel of medical experts for the selection of recipients. Generally, patients 55 years of age or over are excluded from consideration, as are patients that have complicating health conditions in addition to end-stage cardiac disease (e.g., severe pulmonary hypertension, kidney disease, diabetes, etc.). It is noteworthy that:

- Diseases of the heart and blood vessels have been the major cause of death in the United States for more than 40 years.
- There are 42,750,000 Americans with one or more forms of heart or blood vessel disease.
- In 1981, 984,610 people died with cardiovascular disease.

Not all of these people would necessarily benefit from heart transplantation. The following represent a refined set of estimates:

- Approximately 14,000 people die each year of conditions for which heart transplantation is indicated, but most of these people would meet only minimal patient-selection criteria.
- Of these 14,000 people, about 1,900 could meet the most stringent patient selection and be declared as candidates for a heart transplant.
- Of those who are current Medicare beneficiaries, it is estimated that fewer than 1,000 would be suitable candidates for heart transplantation.

Availability of donor hearts

The supply of donor organs is a key factor in determining the number of heart transplants that may be performed each year. This supply of suitable donor organs is severely limited by numerous clinical contraindications to heart donation as well as various attitudinal factors including the willingness of individuals to donate organs for transplantation.

- Considering current selection criteria, the maximum annual number of potential heart donors is approximately 16,000 (representing less than 2 percent of all in-hospital deaths).
- Based on various attitudinal data, it is further estimated that, at most, only 7,000 to 9,000 hearts are available each year for transplantation.
- More realistically, because only 15 percent to 40 percent of all kidney donors may be acceptable heart donors, the number of donor hearts available through the existing network of organ procurement programs could be as high as 850 or as low as 325.

Survival of heart transplant recipients

The survival of heart transplant recipients has improved steadily since the late 1970's. Some of this improvement has been attributed to new immunosuppressive drugs and techniques, although refinements in patient selection criteria have also been a factor.

- Nearly 80 percent of all transplant recipients will live at least 1 year, with approximately 50 percent surviving 5 years.
- It is projected that nearly 25 percent of all heart transplant recipients will live 10 years or longer.
- Patients who have been selected as candidates for heart transplantation but who fail to receive one because of the lack of a donor heart live approximately 40 days.

Quality of life

It is difficult to assess the quality of life of people who are chronically ill. This is particularly true of patients with terminal conditions whose lives have been saved by a heart transplant. Moreover, the objective quality of life of patients may differ substantially from their subjective impressions of it.

- Currently 31.6 percent of all living transplant recipients are working, compared with 8.1 percent at the time of evaluation for transplant. During the year prior to transplant, 46.1 percent of the patients were working.
- The staff of heart transplant centers indicate that 66.3 percent of living heart transplant recipients are "normal: no complaints: no evidence of disease."
- 57.9 percent of the patients describe themselves as being able to work.
- In terms of the subjective aspects of quality of life, such as well-being and life satisfaction, heart transplant recipients compare reasonably well with kidney transplant and kidney dialysis patients who, in turn, compare well with people in the general population.

Cost of heart transplantation

Heart transplantation is an expensive procedure to undergo, although it compares well with the expenditures associated with other accepted forms of treatment for a variety of end-stage diseases. There is a wide variation in the total first-year costs associated with heart transplantation across all transplant programs. All cost summarized below are costs to Medicare and are based on the average case across all centers participating in the study.

- Assuming a 1-month period of candidacy while awaiting transplantation, pretransplant cost averaged \$9,851.00.
- Costs associated with the transplant procedure itself, assuming the patient lives, averaged \$75,085.00.
- Post-transplant costs for survivors for the first year averaged \$9,535.00 and \$6,261.00 per year thereafter.
- The total first-year cost associated with heart transplantation, assuming a 1-month candidacy period, averaged \$94,470.00.
- The base cost of dying as a result of treating end-stage cardiac disease in the absence of a heart transplant is estimated to range between \$6,000 and \$18,000 and to average at least \$9,000.00.

The cost of immunosuppressive drugs, such as cyclosporine, are excluded from these estimates because such drugs are not currently covered by the Medicare program. (This could add about \$5,000 to the post-discharge annual cost.) The following summarizes the overall programmatic implications of Medicare reimbursement for heart transplantation, given the current supply of donor organs and prevailing patient-selectin criteria.

- The cost to Medicare of covering heart transplantation could be relatively small—from \$2.0 to \$3.5 million (in 1983 dollars) per year in the period 1985-89.
- Even with expanded coverage (i.e., relaxing Medicare entitlement criteria for patients with end-stage cardiac disease), the annual cost remains less than \$50.0 million.
- With greater volume and expanded coverage, it is estimated that total expenditures in 1989 would be about \$120.0 million for some 3,200 beneficiaries.

Sources of payment

A chief concern among heart transplant recipients is payment of their medical expenses. During the past 2 years, private insurers have assumed an increasingly greater role in the payment of heart transplants. Based on a survey of heart transplant recipients, it is evident that private insurers have made a substantial commitment to heart transplantation.

- Nearly 55 percent of all living heart transplant recipients have had assistance from private insurers in the payment of their transplant expenses.
- Research funds obtained by transplant centers have been used to assist 30 percent of all living patients.

Diffusion of heart transplantation

Coverage of heart transplantation by private and public insurers is likely to be greeted by a diffusion of the procedure to other medical institutions and a concomitant increase in the number of procedures performed. Several leading heart transplant surgeons, however, have expressed concern about the proliferation of programs. In a survey of all hospitals in the United States with open-heart surgery facilities, the following was determined:

- Within the next 5 years, 119 medical centers are likely to initiate heart transplant programs.
- With Medicare coverage, 198 medical centers have plans to embark on heart transplantation.
- Given the current supply of donor organs, and an optimal level of transplant activity at each center, it is estimated that 43 heart transplant centers would be sufficient for the United States.

Related publications

The volumes of the final report entitled, "National Heart Transplantation Study" are available only from the National Technical Information Service, Document Sales, 5285 Port Royal Road, Springfield, Va. 22151, (703) 487-4650.

As of June 1, 1985, NTIS has imposed a \$3.00 handling fee on all publications.

Ordering information is as follows:

Item	NTIS number	Hard copy	Microfiche
Executive summary	PB 85 213 213/AS	\$16.95	\$5.95
Volume 1 History, Methodology	PB 85 213 221/AS	\$52.95	\$13.50
Volume 2 Need, Supply	PB 85 213 239/AS	\$52.95	\$13.50
Volume 3 Survival, Quality of Life, Cost	PB 85 213 247/AS	\$34.95	\$ 5.95
Volume 4 Legal, Ethical	PB 85 213 254/AS	\$46.95	\$ 5.95
Volume 5 Miscellaneous, Bibliography	PB 85 213 262/AS	\$52.95	\$13.50
Volume 1-5	PB 85 213 205/AS	\$240.75	\$52.40

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